Transonic Systems Inc.
Excellence in Quantitative Hemodynamics

FEB 11 1997

Supplement 2, Appendix 2. **510(K) SUMMARY** **# K960817**
(Revision dd. Nov. 12 1996)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92, by:

Contact Person: Cornelis J. Drost, President
Transonic Systems Inc.
34 Dutch Mill Road
Ithaca NY 14850
Phone: (607) 257-5300

2.1 Device Identification & SE Claims.

Trade name: TRANSONIC HD01-SERIES HEMODIALYSIS MONITOR
Common name: Hemodialysis monitor

Devices in this model family:	*Model name:*	*Legally marketed device to which SE is claimed:*
Access recirculation monitor:	HD01-R%	BUN on Boehringer Mannheim Hitachi 911 Analyzer
Access flow monitor	HD01-QA	Philips P700 ultrasound system with CVI-Q option
Delivered bloodflow monitor	HD01-QB	Fresenius 2008 Dialysis System (pump readout only)

2.2 Device Description.

The following measurements can be made with the HD01:

Access recirculation: The percentage of dialyzed blood delivered by the venous needle that traverses the access device in reverse direction to be removed again via the arterial needle.

Access flow: The rate of blood flow in mL/min entering the native fistula or artificial graft at the site of the arterial needle.

Delivered blood flow: The rate of blood flow, in mL/min, in the hemodialysis venous blood line.

The HD01 uses transit-time ultrasound principles to make the flow measurements and register sound velocity indicator dilution curves. Standard Stewart-Hamilton equations are employed for the various calculations. Portions of these technologies are covered under Transonic Systems' USA and worldwide patents and patents pending.

All Transonic HD01-series hemodialysis monitor devices consists of the following components:

* "HD01 flow/dilution meter" or "HD01 meter": A bench-top, line power operated electronic measurement unit with serial RS232 data output link;

* "Dual flow/dilution sensor", individually referred to as "arterial sensor" and "venous sensor": Two plastic-encased ultrasonic sensors, connecting to the HD01 unit, to be clipped onto the patient arterial and venous hemodialysis blood lines;

* "Monitor software" also referred to as "software": Computer software to be installed on an IBM-PC compatible computer, which performs the various device function calculations (R%, QA etc.) from the signals produced by the HD01 meter.

The various HD01 devices differ in their indications for use through the supplied software routines. For a combination device with all the monitor functions a trained medical operator may select the following measurements:

2.2a. Access recirculation measurement:

A volume of about 5 ml of 0.9% saline is injected before the venous line bubble trap, using standard sterile procedures. The venous transit time sensor identifies the resulting indicator dilution curve. The monitor also analyzes the arterial sensor signal during the time where the venous bolus can directly recirculate (via access device or catheter) to the arterial line, but *before* cardiopulmonary recirculation can take place (i.e. *before* the same bolus recycles through the heart into the arterial line). If direct recirculation is identified, the meter calculates flow-corrected "access recirculation" from the areas of these two indicator dilution curves and the instantaneous flow in the blood lines.

2.2b Access flow measurement:

For this measurement the two blood lines are reversed at the point where the two hemodialysis needle tubings are connected to the hemodialysis blood lines, employing the flow clamps present on the lines and standard patient care procedures. The access flow measurement is made upon injection of about 10 ml of 0.9% saline in the same injection port of the venous blood line (before the bubble trap); the venous sensor records its indicator dilution curve. The injected bolus now enters the patient via the arterial needle, which much be placed facing upstream in the artery to assure complete mixing. The venous needle samples the indicator concentration in the mixed blood stream; the arterial line sensor registers its indicator dilution curve. The sensors also record the instantaneous blood flow through the lines. The HD01 calculates the flow through the access device from the ratio of these two indicator dilution curves and the instantaneous delivered bloodflow.

2.2d Delivered bloodflow:

This flow reading is continuously displayed on a digital display of the HD01 unit. Whenever an indicator dilution measurement is made the reading is also reported on the computer display.

K960817
P307

2.3 Intended Uses of the HD01-series of Devices.

The HD01-series monitors are intended for use by trained medical personnel on patients receiving hemodialysis treatment, for the routine monitoring of the following patient and blood handling diagnostic parameters:

Access recirculation: a check on proper dialysis needle placement and dialysis pump setting in relation to flow in the access device. Access recirculation would prevent the patient of receiving its full hemodialysis prescription. Access recirculation that cannot be mitigated by altering needle placement should be referred to the attending physician, for a change in the patient hemodialysis prescription and as a possible indication of deteriorating flow in the access device.

Access flow: allows the routine monitoring of patency of the access device. A substantial decrease in flow passing through the shunt or fistula from the initial level may indicate deterioration of the access, and should be referred to the attending physician for further diagnostic assessment and treatment.

Delivered bloodflow: a check on the hemodialysis pump setting, to confirm that the patient receives the hemodialysis treatment prescribed by the attending physician.

Contraindications:

The H4D dual flow/dilution sensor is for clip-on use only onto the sterile tubing specific to the flow sensor, and never on arteries or veins.

Safe and effective use of these devices depend on correct application technique, adequate precaution and readiness for emergencies.

Caution: Not intended for fetal or ophthalmic use.

Caution: Federal law resticts this device to sale by or on the order of a physician.

2.4 Summary of Technological Comparison with Predicate Devices.

Access recirculation monitor:

The Transonic HD01-R% device uses transit-time ultrasound indicator dilution sensing technology.

A BUN-recirculation measurement done with the Boehringer Mannheim Hitachi 911 Analyzer consists of: taking three blood samples from the patient during hemodialysis; analyzing these samples on the Hitachi 911 for blood urea nitrogen level; calculating access recirculation from the three BUN levels.

Access flow monitor:

The Transonic HD01-QA device uses transit-time ultrasound indicator dilution sensing technology, and transit-time ultrasound flow sensing technology.

The Philips P700 ultrasound system with CVI-Q option uses time domain Doppler ultrasound to measure average bloodflow velocity in the vessel, and the cross sectional area of the vessel by ultrasound sonography.

Delivered bloodflow monitor:

HD01-QB device uses transit-time ultrasound indicator dilution sensing technology, and transit-time ultrasound flow sensing technology.

Fresenius 2008 Dialysis System converts the RPM of the hemodialysis pump into a readout of flow, under the assumption that the tubing cross sectional area is a constant.

2.5 Safety.

The HD01-series devices meet all requirements of:

* UL544 & IEC 601-1;
* The European Economic Council Directive 89/336/EEC (electromagnetic compatibility);
* Ultrasound intensity levels applied by the H4D clamp-on flow/dilution sensors are 25 to 40 dB below FDA CDRH maximum pre-amendment levels for "Fetal Dopper and Other" applications.

All procedures required to execute these measurements (saline injection, change in blood line connections) are standard clinical procedures in which hemodialysis nurses are well trained.

The HD01 procedures introduce no extra components into the hemodialysis circuit; at no place is patient sterility compromised.

2.6 Effectiveness.

Since it's introduction in November 1994, the following publications have appeared in print to attest to the effectiveness of these hemodialysis monitoring methods. (Numbers refer to the ordering in 510(k) Appendix 10, and the additional numbers in Supp.1 App.5)

Access recirculation

8. Depner, T.A., Krivitski, N.M., MacGibbon, D., "Hemodialysis Access Recirculation (Rc) Measured by Ultrasound Dilution", ASAIO Journal, Vol. 41, p. M749-M753, 1995.
12. George, T.O., Priester-Coary, A., Dunea, G., Daugirdas, J.T., "Access Recirculation (AR) by Ultrasonic Dilution Compared to a 20 Sec Slow Flow Urea Method", Am.Soc. of Nephrol. Abstr. p. 489, 1995.
15. Krivitski, N.M., "Accuracy of Hemodialysis Access Recirculation Measurement", "Vascular Access for Hemodialysis V", A Symposium on Dialysis Access, Abstract (in press).
35. MacDonald, J., Sosa, M., Nudo, S., Glidden, D., Sands, J.J., "Identifying a new reality: Zero Access Recirculation", American Nurses Association Journal, Vol. 23, No.2, p. 172, 1996.
28. Sands, J., Krivitski, N.M., "Access Recirculation in Hemodialysis" , "Vascular Access for Hemodialysis V", A Symposium on Dialysis Access, Abstract (in press).
36. Subra, J.F., Choulet, P., Tollis, F., Trouvé, R., Riberi, P., "Hemodialysis Access Recirculation Evaluation by Ultrasonic Dilution Method," Europ. Dial. & Transpl. Assoc. Abstracts, p. 287, 1996.
37. Visser, C.A., Kloppenburg, W.D., deJong, P.E., Huisman, R.M., "Access Recirculation in Hemodialysis detected by Ultrasound Dilution and Urea Dilution Methods," Eur.Dial.& Transpl.Assoc.Abs. p.297, 1996.

Access flow

5. Bosman, P.J., Boereboom, F.T.J., Bakker, C.J., Mali, W.P., Eikelboom, B.C., Blankenstijn, P.J., Koomans, H.A., "A New Fick-Principle Based Method for Measuring Blood Flow in Hemodialysis Grafts Validated by Magnetic Resonance Angiography", American Society of Nephrology Abstracts, p. 484, 1995.
7. Depner, T.A., Krivitski, N.M., "Clinical Measurement of Blood Flow in Hemodialysis Access Fistulae and Grafts by Ultrasound Dilution", ASAIO Journal, Vol. 41, p. M746-M749, 1995.
10. Dobson, A., Harvey, H.J., Gleed, R.D., "Validation in Sheep of the Ultrasound Dilution Technique for Hemodialysis Graft Flow." Abstract, ASAIO Vol.. 42, No.2, p.81, 1996.
19. Krivitski, N.M., "Novel Method to Measure Access Flow during Hemodialysis by Ultrasound Dilution

K960817
p 5 of 7

Technique", ASAIO Journal, Vol. 41, p. M741-M745, 1995.
20. Krivitski, N.M., "Theory and Validation of Access Flow Measurement by Dilution Technique during Hemodialysis", Kidney International, Vol. 48, p. 244-250, 1995.
33. Krivitski, N.M., Dobson, A., Gleed, R.D., "Vascular Access Flow Changes with Normal or Reversed Hemodialysis Blood Flow," ASAIO Journal Abstracts, Vol. 42, No.2, p.80, 1996.
24. Sands, J.J., "Blood Flow Measurement in PTFE Hemodialysis Grafts by Ultrasound Velocity Dilution", American Society of Nephrology Abstracts, p. 501, 1995.
26. Sands, J.J., Glidden, D., Miranda, C., "Access Flow Measuremed during Hemodialysis," ASAIO Abstracts, Vol 42 p.80, 1996.
27. Sands, J.J., Glidden, D., Miranda, C., "Hemodialysis Access Flow Measurement - Comparison of Ultrasound Dilution and Duplex Ultrasonography," ASAIO Abstracts, Vol 42, No.2, p. 76, 1996.

Delivered bloodflow:

Transonic Systems' transit-time flowmetering using sterile tubing clamp-on sensors is a mature technology, well-proven in independent customer validations over the past several years. One such validation of the Transonic probe was compared with a hemodialysis pump and volumetric (beaker-stopwatch) calibration is:

9. Depner, T.A., Rizwan, S., Stasi, T.A., "Pressure effects on roller pump blood flow during hemodialysis", ASAIO Journal, May 1990.
25. Sands, J., Glidden, D., Jascavage, W., "Difference between Delivered and Prescribed Blood Flow (Qb) in Hemodialysis", Abstract, ASAIO Vol.42, No.2, p.76, 1996.

Summary comparisons between the HD01 devices and the predicate devices:

	3-Sample BUN recirculation on B. M. Hitachi 911 Analyzer	Transonic HD01-R%
Indications:	Hitachi 911 is for measurement of blood urea nitrogen in blood samples; personnel calculates recirculation from three blood samples.	For assessment of adequate delivery of undialysed blood into HD machine from native fistula, artificial graft or catheterized veins.
Effectiveness		
Absolute Accuracy	Clinical zero recirculation offset: 3 to 12% Accuracy at higher recirculation levels: not available	Clinical zero recirc. accuracy: ± 2 % Accuracy at higher recirculation levels: The larger of: ±2% or ± 5% of reading (bench-validated)
Repeatability	Clinical data: 2% ± 14.4% 20% ± 9.6% 40% ± 3.6% Clinical correlation coefficient .81	absolute, bench: 2% ± 2% 20% ± 2% 40% ± 2% Clinical correlation coefficient .98

K960817
p6 of 7

	Color doppler duplex sonography Philips P700 w. CVI-Q option	Transonic HD01-QA
Indications:	For the transcutaneous measurement of bloodflow in arteries and veins	For measurement of blood flow in native HD fistula or HD artificial grafts.
Safety:		
Ultrasonic	Operator must ensure that maximum Ultrasonic irradiation levels are not exceeded for specific applications.	Ultrasonic irradiation level is 320 times lower than CDRH permitted level for peripheral vessel use. (See appendix 2)
Effectiveness		
Accuracy	± 14%, subject to tight alignment and operator training conditions	± 50 ml/min or ± 15% of access flow, whichever is larger.
Repeatability	clinical: correlation coefficient = 0.52	clinical: correlation coefficient = 0.978, mean absolute error = 5.0 ± 3.8%

	Fresenius 2008 Dialysis System: dialysis pump performance	Transonic HD01-QB with H4D clamp-on sensor
Indications:	To adjust and monitor delivered bloodflow in the Fresenius 2008 Dialysis System	To measure flow through sterile tubing used in extracorporeal blood systems, such as hemodialysis blood lines.
Effectiveness		
Total accuracy	Pump calibration is done by converting RPM into indication of flow. No accuracy tolerance is specified for changes in tubing inside diameter and inlet pressure. Literature cites up to 50% error in flow indication before tubing collapse is visually evident (Depner[9]).	±6% of flow reading + zero offset; Max. zero offset = ±8 ml/min (adjustable to zero) Total combined error: ± 8% for a typical flow in 400 ml/min. range

K960817 p7/7

	Transonic T101D/T201D with 8C clamp-on flow probe	Transonic HD01-QB with H4D clamp-on sensor
Indications:	To monitor instantaneous and average volume flow of blood or other liquids through standard laboratory tubing used with adult and pediatric patients. Cited examples are: CP bypass, ECMO, hemodialysis, A-V hemofiltration.	To measure flow through sterile tubing used in extracorporeal blood systems, such as hemodialysis blood lines; To make differential comparisons between removed and delivered flow.
Safety:		
Method:	Transit-time ultrasound using clamp-on sensors applied onto patient blood lines	Identical
Electrical:	ETL listed to meet UL544 specs: Input leakage current < 100 μA Patient leakage current < 10 μA	Meets UL544 specs: Input leakage current < 50 μA Patient leakage current < 10μA Patient isolation > 2500V
Ultrasonic	Ultrasonic irradiation level is 175 times lower than CDRH permitted level for peripheral vessel use. (See appendix 9)	Ultrasonic irradiation level is 320 times lower than CDRH permitted level for peripheral vessel use. (See appendix 2)
Effectiveness	(with predicate 8C probe for 1/2"OD tubing)	(w. H4D sensor for 1/4" OD tubing)
Total accuracy	$\pm$5% of flow reading + zero offset; Max. zero offset = $\pm$50 ml/min - (adjustable to zero)	$\pm$6% of flow reading + zero offset; Max. zero offset = $\pm$8 ml/min (adjustable to zero)
Max.relative error	$\pm$2% of flow reading + zero offset	$\pm$2% of flow reading + zero offset
Typical flow resolution	5 ml/min	1 ml/min
Flow range	-10 to 10 L/min	-2 to +2 L/min

2.7 Summary of Safety and Effectiveness.

The bench and clinical tests cited above demonstrate that, like the predicate devices, the HD01-series of hemodialysis monitors is safe and effective for its intended use.

Cornelis J. Drost,
President
Transonic Systems Inc.
34 Dutch Mill Road
Ithaca NY USA 14850

Nov. 12, 1996
Preparation date